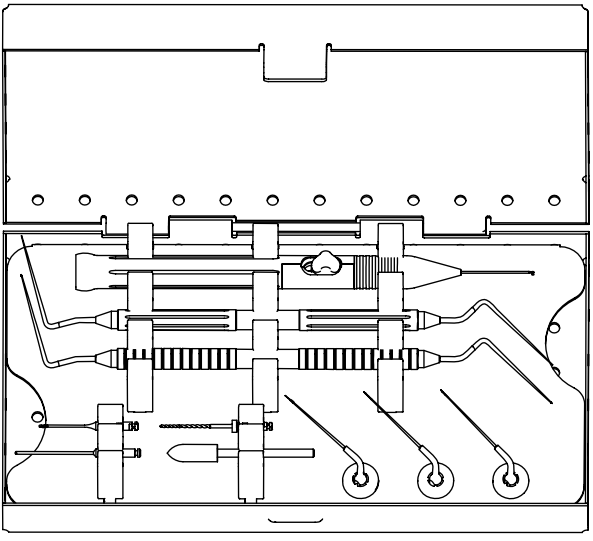
Terauchi File Removal Kit Instruction Manual

Thank you for purchasing the Terauchi File Removal Kit(TFRK) produced by Guilin Woodpecker. In order to ensure the correct use of the machine, we recommend that you carefully read this Manual about installation, operation, maintenance and inspection before use. For your convenience, it is recommended that you keep this Manual in a readily accessible place.



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www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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Guilin Woodpecker Medical Instrument Co., Ltd is a manufacturer specializing in the development and manufacture of dental products. Woodpecker owns a sound quality control system and four brands, Woodpecker, DTE, DBA and RTA. The main products include Ultrasonic Scaler, Curing light, Apex locator, Ultrasurgery, Endo Motor, and Dental Electric Motor, etc.

1 Introduction

The Terauchi File Removal Kit(TFRK) consists of Autoclavable Cassette, Endo file remover(TFRK-L), Dental Explorer(TFRK-ME and TFRK-GPR), Dental Root Canal Instruments(GATE DRILLS #3, K-ENDO K6 N60 2% L25 and Trephine TFRK-MT), Tips of Ultrasonic Scaler(E87/E88/E89 or ED87/ED88/ED89) and Polishing rod(TFRK-P). It is intended for removing broken files from the root canal.

1.1 Precautions before operation

Warnings:

1.1.1.A severe impact, such as a drop from high position, can result in damage to the devices.

1.1.2.Sterilize before use.

1.1.3.For professional use only.

1.2 Intended use/Indications for Use

The Terauchi File Removal Kit(TFRK) consists of Autoclavable Cassette, Endo file remover(TFRK-L), Dental Explorer(TFRK-ME and TFRK-GPR), Dental Root Canal Instruments(GATE DRILLS #3, K-ENDO K6 N60 2% L25 and Trephine TFRK-MT), Tips of Ultrasonic Scaler(E87/E88/E89 or ED87/ED88/ED89) and Polishing rod(TFRK-P). It is intended for removing broken files from the root canal.

1.3 Models

TFRK

1.4 Contraindications

None known.

1.5 Cautions

1.5.1.Patients with heart disease and children should be cautious to use this device.

1.5.2. Patients with mental disturbance should be cautious to use this device.

1.6 Safety requirements

Guilin Woodpecker Medical Instrument Co., Ltd. will not be liable for any direct or indirect damages and losses under the following conditions:

• The device is used for any purpose other than the mentioned scope of application.

• The operator did not use the device in accordance with the procedures and requirements stipulated in the Instruction Manual.

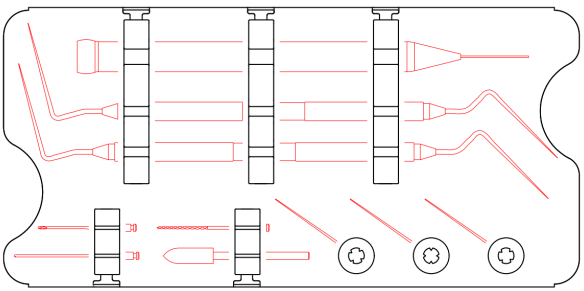
• Assembling, operating, and repairing the device without the authorization of the Woodpecker.

• The environmental conditions in which the device is located or stored do not meet the requirements mentioned in the section on technical requirements.

2 Product composition

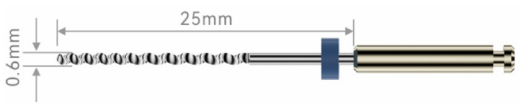
2.1 Autoclavable Cassette

The Terauchi File Removal Kit (TFRK) comes in an autoclavable metal box that opens to access all instruments.



2.2 Dental Root Canal Instruments

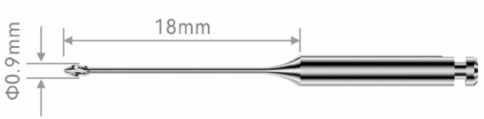
2.2.1.K-ENDO K6 N60 2% L25



Martensitic-phased NiTi Rotary Instrument K-ENDO K6 N60 2% L25. 60%, 2% taper, NiTi file in the martensitic phase at 37℃.

If the coronal diameter of the broken file is >0.45 mm or the canal curvature is >15˚, use this rotary instrument to enlarge the canal to the broken file at 500 rpm counterclockwise.

2.2.2 GATE DRILLS #3



If the coronal diameter of the broken file is < 0.45 mm or the canal curvature is < 15°, use this instrument to enlarge the canal to the broken file.

The pilot tip of the GATE DRILLS #3 is cut off so that the root canal to the broken file can be enlarged to at least 0.45 mm as the tip diameter of the GATE DRILLS #3 is 0.45 mm. It is used at 2500 rpm clockwise with a brushing motion against the outer wall to create a funnel shape.

2.2.3 Trephine TFRK-MT

Inner diameter of the TFRK-MT is Φ0.5mm whereas the outer diameter

of the TFRK-MT is 0.8 mm.

TFRK-MT can be used when the canal curvature is <15˚and the coronal diameter of the broken file is < 0.45 mm. The inner depth of the TFRK-MT is 1 mm to expose a 1 mm-portion of the broken file. Spin the TFRK-MT at 600 rpm counterclockwise in a short in/our motion to expose the coronal 1 mm-portion of the broken file after the canal enlargement with the GATE DRILLS #3 rotating at 2500 rpm to the broken file. If the canal curvature is >15˚, the K-ENDO K6 N60 2% L25 NiTi rotary file should be used to enlarge the canal to the broken file.

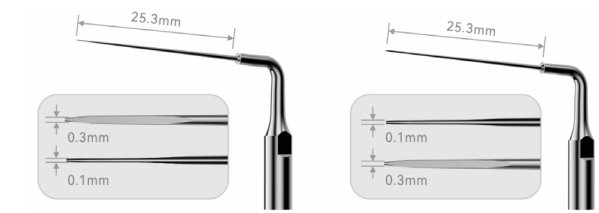
If the coronal diameter of the broken file is > 0.45 mm or the canal curvature is > 15°, the TFRK-MT should not be used, and the TFRK tips should be used directly to prepare the space.

2.3 Tips of Ultrasonic Scaler

There are one straight tip (E87/ED87) and two sword-shaped tips (E88/ED88 and E89/ED89) in the TFRK. These ultrasonic tips are carefully bent to meet the fractured file surface on the inside of the canal curvature. The Polishing rod is used to sharpen the E87/ED87 every time it is used.

E87、E88、E89 ultrasonic tips are compatible with UDS ultrasonic scaler, and ED87、ED88、ED89 ultrasonic tips are compatible with DTE ultrasonic scaler.

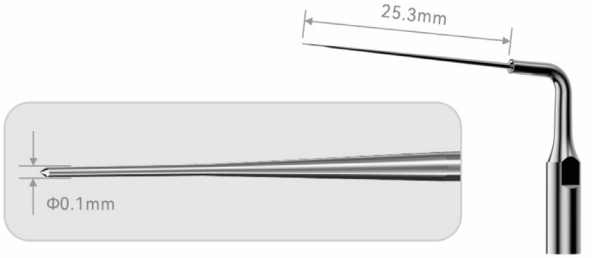
2.3.1 E88/ED88 & E89/ED89



E89/ED89 E88/ED88

The E88/ED88 and E89/ED89 ultrasonic tips are designed with an extremely thin sword-shaped head. Activate ultrasonics with the flat surface directed to the broken file from the inner wall of the canal. The E88/ED88 and E89/ED89 ultrasonic tips are used (dry) to wedge into the space on the inside of the canal curve between the separated file and the canal wall, creating a small space adjacent to the fractured file edge. After the initial use of the E88/ED88 or E89/ED89 tips to cut a semicircular slot next to the file segment, use the E87/ED87 tip to complete the semicircular space as the E88/ED88 or E89/ED89 tips usually cut only a quarter slot of the circle. The ultrasonic preparation continues until the movement of the broken instrument is confirmed under the magnification.

2.3.2 E87/ED87



E87/ED87 is characterized by an extremely sharp cone-shaped tip: 0.1 mm diameter tip with 1% taper that can be pre-curved to be adapted to the canal curvature.

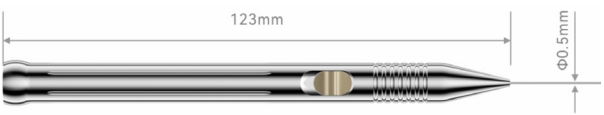
Feature 1: Extend the grooved space to a 180˚semicircular ditch until the broken file is seen dancing after the 90˚ semicircular space created on the inner wall with the E88/ED88 or E89/ED89.

Feature 2: Remove the broken file.

Feature 3: Create a thin space between the canal wall and gutta-percha root fillings for the introduction of the TFRK-GPR.

Feature 4: Remove necrotic pulp tissues and debris from an isthmus or a thin space.

2.4 Endo file remover(TFRK-L)



Used to retrieve the broken file after loosening it in preparation with ultrasonics when the broken file is longer than 4.5 mm or the broken file did not come out with ultrasonics in 10 seconds at removal attempts. The loop size is adjusted to the diameter of the broken file with an endodontic explorer and bent to 45 degrees to facilitate the placement of the loop over the broken file. The loop cannula is replaceable. The damaged loop can be quickly and easily replaced with a new loop. There are two sizes of the loop wire: 0.12 mm and 0.08 mm, suitable for different clinical situations with varying root canal diameters and resistance.

The maximum diameter of the microtube holding the loop is 0.5 mm and it has a 23 mm length. The microtube can be pre-curved to facilitate its placement into the root canal.

The Endo file remover is a fragile device, and with proper care is very effective. Please keep the following in mind when using the loop:

1.The broken file must be loosened in the canal with the TFRK ultrasonic tips before using the Endo file remover. The loop will not be able to pull out a broken file that is still stuck in the canal; attempting this will break the loop before the file will exit the canal.

2.When engaging the plastic button to tighten the lasso, move the button very gently. Abrupt movement can kink the lasso and break or weaken the micro-wire loop.

3.Engage the lasso only after securing the broken file; unnecessary tightening and loosening of the lasso will shorten its lifespan.

4.Use your gloved fingers to bend the tube portion as needed. Using

pliers will pinch the structure and break it.

5.Use a endodontic explorer to form and adjust the loop size. Place the loop over the tip portion of the explorer to make the loop size smaller, the middle portion of the explorer to make it medium, and the shank end of the explorer to make it larger.

6.Bend the formed loop to 45 degrees by rotating the endodontic explorer it is formed around to be parallel to the cannula. This angle imparted to the formed micro-lasso will facilitate its placement over the separated file.

2.5 Dental Explorer

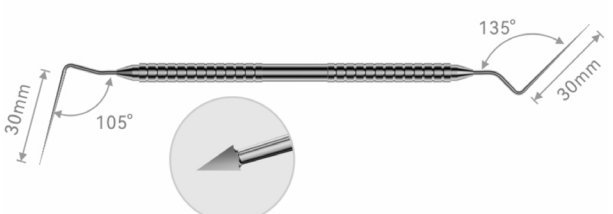
The Dental Explorer have two ends that are extra long and are angled obtusely and acutely to accommodate different canal angles.

2.5.1 TFRK-ME

Made of stainless steel, a sharp 0.1mm-tip-diameter explorer, double ended, 6% taper, smooth-surfaced.

The TFRK-ME has extremely fine spear-shaped tips with a smooth surface for bypassing ledged canals and exploring the canal for broken files or other impediments. This instrument can be bent to meet the canal curvature so that the TFRK tips can be precurved the same way as it is before use. When there is a ledge formed coronal to the separated file in the canal, the TFRK-ME can be used to locate the original canal and the ledge can be reduced by using it with several push-pull strokes. When the tip portion gets short or blunt, it can also be sharpened with the Polishing rod in the kit.

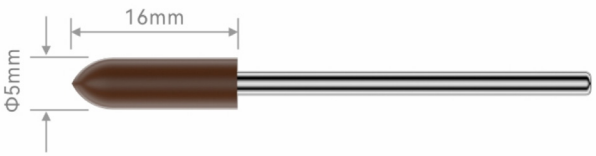
2.5.2 TFRK-GPR



Made of stainless steel, 4% taper. With arrow-shaped barbed cones (max. diameter: 0.35mm) on both end.

The TFRK-GPR has arrow-shaped barbed cones on both ends to engage filling material remnants during removal procedures. Necrotic pulp tissues or debris in a narrow space such as an isthmus or a fin can also be removed with this Instrument. It is bendable to fit the canal curvature. Smaller size pyramidal tip can make it very easy to scrape gutta-percha root fillings from the canal wall.

2.6 Polishing rod(TFRK-P)



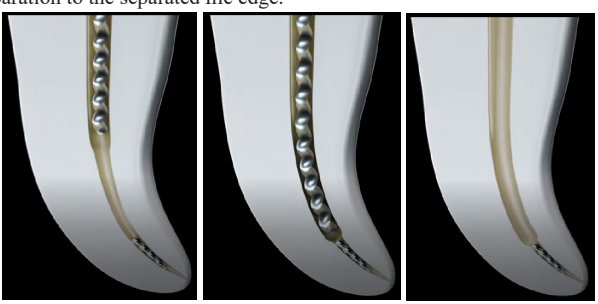
The Polishing rod can polish the tips of E87/ED87 and TFRK-ME, making them sharp.

3 The Terauchi File Removal Techniques

3.1 Using K-ENDO K6 N60 2% L25 file

For Separated Files with Coronal Diameters greater than 0.45 mm. or Canal Curvature greater than 15 degrees.

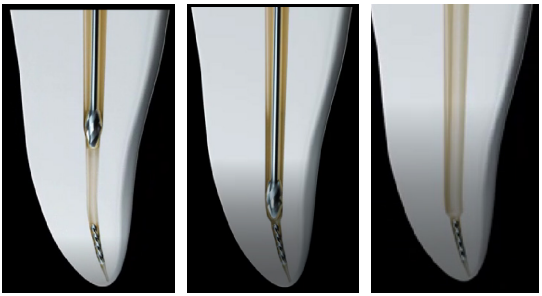
If the coronal diameter of the separated file appears to be larger than 0.45 mm (this can be determined by gauging with a #45 K-file or Buchanan Pluggers placed on the separated file), or the canal curvature is greater than 15 degrees, use the K-ENDO K6 N60 2% L25 File included in the TFRK (instead of the GATE DRILLS #3 or TFRK-MT burs) to cut a staging preparation to the separated file edge.



3.2 Using the GATE DRILLS #3 Bur

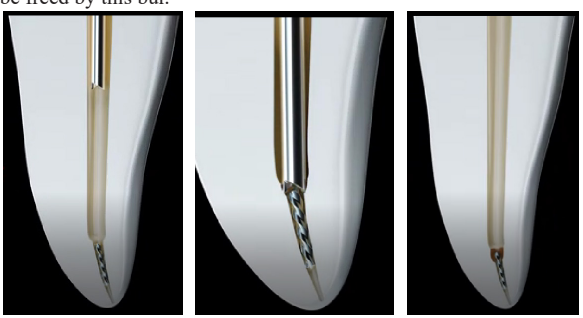
For Separated Files with Coronal Diameters less than 0.45 mm, or Canal Curvature less than 15 degrees.

If the coronal diameter of the separated file appears to be smaller than 0.45 mm, (this can be ascertained by gauging the canal space just behind the broken edge of the separated instrument) use the GATE DRILLS #3, to create working space for the TFRK-MT bur, which will cut the canal wall to expose the coronal portion of the file segment. Using the GATE DRILLS #3 bur at this point will reduce the risk of ledge formation with the TFRK-MT bur. In addition to this frequently observed incidence, users are cautioned that aggressive ultrasonic troughing around the separated file prior to use of the TFRK-MT bur may result in secondary fracture of the file segment.



3.3 Using the TFRK-MT Bur

Use the GATE DRILLS #3 bur in a clockwise motion at 1000 RPM and the TFRK-MT bur in a counter-clockwise motion at 600 RPM; this CCW rotation imparts an unscrewing effect on the separated file which can then be spun out of the canal. If the rotational speed of the bur exceeds 800 rpm, you run the risk of creating a ledge, especially in a curved canal. Especially when the separated file is less than 3 mm, theoretically it may possibly be removed with the TFRK-MT bur as the coronal 1 mm of the separated file can be freed by this bur.



3.4 Using the Tips of Ultrasonic Scaler

(After using the GATE DRILLS #3 and TFRK-MT Burs)

After the canal preparation for instrument Removal with the GATE DRILLS #3 and TFRK-MT burs, the next step is to use ultrasonic tips to complete the root canal preparation. Use of those burs in the previous steps should have exposed the coronal portion of the separated file. However, the space created on the inner curve still needs to be extended in the apical direction with the TFRK ultrasonic tips.

TFRK Ultrasonic tips are best tuned to ideal power settings by beginning their use at the lowest power setting and gradually increasing the power until resonance is achieved. These are perhaps the smallest ultrasonic tips in dentistry, and as such will not withstand a high setting (medium power is high for these tips), nor is it necessary to make them cut effectively. For D600 scaler, a setting of 1(E mode) out of the full power range of 10 is typically an ideal setting.

In most cases, the coronal one third of the separated file is the source of removal complications: this portion is usually surrounded by the canal wall, susceptible to secondary breakage, and resistant to mechanical force

for disengagement. It must be freed from its engagement in dentin before attempting separated file removal. Creating a thin space on one side (always the inner side of a curved canal) is large enough to loosen the separated file instead of toughing around it. Freeing the coronal one third of the separated file must be done in dry conditions using air coolant to both maintain clear vision and to cool the ultrasonic tip in the operative field.

These tip have very elongate geometry, and as such, should not be operated unengaged (held free in air while switched on) as the sine wave of vibration that ripples down the long, narrow stalk in an unengaged situation will cause premature failure due to cyclic fatigue. The tips require the dampening effect of being in light contact with a hard surface (tooth structure, the U/S wrench included, etc.) as the power setting is tuned and as it is being used. Pulsing activation is recommended while activating ultrasonic in contact with dentin to avoid premature breakage.

3.4.1 Exposing the Coronal Portion of Separated Files with Ultrasonic Tips

If rotary instruments other than the GATE DRILLS #3 and TFRK-MT burs were used to enlarge the canal to the separated file in the previous stage, then you must use ultrasonic tips to manually expose the coronal portion of the separated file. Use the E88/ED88 or E89/ED89 tip around the coronal aspect of the separated file on the inside of the curvature of the canal.

The greatest power achieved between the TFRK tip end and the dentin around the separated file segment is upon its delivery of the first pulse of power. If you can imagine the stalk of this tip sending a wave down its length (somewhat like the childhood game of “crack the whip”), when it arrives at the tip there is a remarkably violent, yet microscopic movement against the dentin canal wall. You will get the greatest amount of troughing around the broken file end and the longest life of the tip when it is used with intermittent power switching, in other words, by “popping” the foot control repeatedly to activate the tip. This method of use delivers optimal movement of the cutting end while reducing the generation of heat and cyclic fatigue accumulation in the instrument (cyclic fatigue accumulates every second it is being powered).

Heat produced by continuous ultrasonic activation is another cause of premature failure, so the intermittent powering suggested will reduce the heat generated and help extend the TFRK tip life as well. Usually it is Ideal to send 1 to 2-second amount of ultrasonic power pulses through the tip with constant air coolant given from the three-way syringe by your assistant to prevent temperature rise. When the separated file is covered with debris, take the tip out and rinse the canal. Wipe the tip with alcohol gauze, which will provide the time to bring the heated tip back to the room temperature. Inspect the tip and sharpen if needed, then put it back into the canal to do more work. The sword-shaped (E88/ED88 and E89/ED89) and the TFRK-S tip E87/ED87 are used dry (bent to work only on the inside of the canal curve) until the file has been loosened, then aqueous EDTA solution is added to take advantage of cavitation effect (turbulence) created by the ultrasonic energy more efficiently resulting in propelling the segment out of the canal with the E87/ED87 tip once again engaged on the inside of the canal curvature only. The activated E87/ED87 tip should be moved in short push-pull motions within the thin space created previously in the presence of EDTA solution to induce the micro-cavitation (micro-turbulence) needed

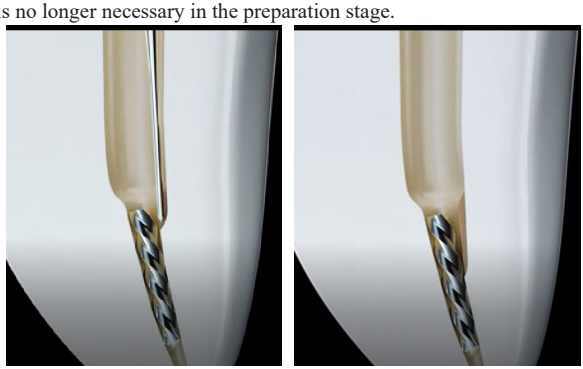
in the canal to encourage the separated file segment to exit the canal. The E87/ED87 tip has to be always sharp and thin to make room for the separated file to exit the canal and it is used in this final wet conditions with the continuous activation mode as the EDTA solution in the canal buffers both the heat rise and the ultrasonic activation. The E87/ED87 tip should be sharpened with the included Polishing rod every time it is used.

Caution! Files may fracture into even smaller pieces: A fatigued separated file is extremely susceptible to secondary fracture by ultrasonic activation, even when ultrasonic tips are at the lowest power setting. To reduce the risk of fracture, cut a semicircular trough on one side (the side of the file segment on the inside of the canal curvature), as this leaves the outside of the curved canal wall to support the file segment, thus reducing the likelihood of secondary file separation. Especially in a curved canal, you should always apply ultrasonic activation to the thin space between the separated fragment and the inside curvature. In other words, the dentin wall supporting the separated file fragment (on the outside of canal curvature) must always be present opposite from the ultrasonic activation site on the inside of the canal curvature to prevent secondary fracture of the file segment.

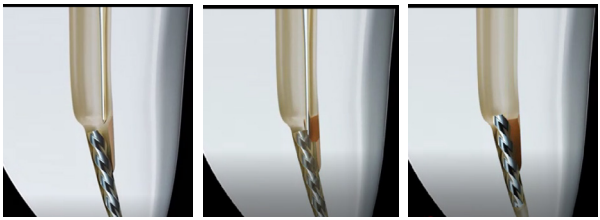
3.4.2 Using the TFRK Ultrasonic Tip to Loosen Files

The E87/ED87 ultrasonic tip used for this purpose should be as thin as possible to maximize visibility in the operative field, prevent over-enlargement of canal wall, and to provide an escape space for the separated file. The thinner the E87/ED87 tip is, the more effectively it creates the micro-cavitation needed, so repeated polishing with the included polishing point is critical to its function.

Use the E88/ED88 or E89/ED89 and E87/ED87 ultrasonic tips to create a semicircular space; the E88/ED88 and E89/ED89 ultrasonic tips have an extremely thin sword-shaped head to wedge between the canal wall and the separated file and dislodge the file. The E87/ED87 tip is used to extend the space apically and laterally to complete the semicircular space and eventually loosen the separated file engaged in the canal wall. If the E88/ED88 or E89/ED89 tip loosens the separated file while preparing the canal, the preparation is considered done. In such a case, the use of the E87/ED87 tip is no longer necessary in the preparation stage.



（Use the E88/ED88 or E89/ED89 and E87/ED87 ultrasonic tips to create a semicircular space）



（Use the E87/ED87 tip to extend the space apically and laterally to complete the semicircular space and eventually loosen the separated file engaged in the canal wall）

When the E87/ED87 tip is wedged in the small space and activated on the inside curvature, it may cause the separated file to be shifted to a more coronal level or completely freed. If the tip is activated on the outside curvature of the canal, the ultrasonic energy will drive the separated file further in an apical direction.

Check for a Smooth Canal Wall: Once a narrow space is established, it is important to make sure that the canal wall is smooth from the separated file to the coronal extent; bumps, impediments, or overhangs on the outside canal wall may block the removal path for the separated file. Use a bent E87/ED87 ultrasonic tip to carefully smooth the canal wall on the outside of the curvature after troughing the inside-of-the-curvature canal wall and loosening the file segment to remove any impediments that can block the escape path for the separated file.

3.4.3 Propelling the Loosened File Segment Out of the Canal

Fill the canal with EDTA solution to enhance the ultrasonic cavitation effect and acoustic streaming for separated file removal.

Warning! Don’t wedge the file fragment further into the canal:

Ultrasonic activation should be applied to the space created between the separated file and the inside curve of the canal in push-pull motions until the file fragment is removed. Remember, when ultrasonic energy is applied to the outside of the canal curvature, the file segment will be driven further apically.

To avoid instrument breakage, use short pecking motions within the thin space as wedging the tip tightly between the separated file and the canal wall when activated will increase the possibility of breaking the thin tip.

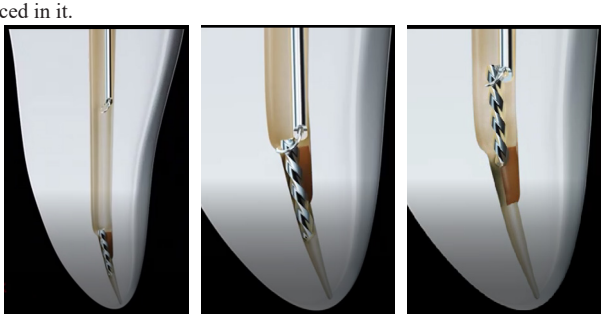
3.4.4 When to Remove More Dentin

If the separated file is shorter than 4.5 mm and it shows resistance to disengagement (no movement with ultrasonics) for more than 60 seconds after the one-third space of the separated file length is created, more dentin wall needs to be cut with the E87/ED87 tip apically along the inside-of-the-curvature wall adjacent to the separated file. In this process, you are deepening (dry) the pocket in dentin wall and loosening the file fragment from the canal wall. Then, again, fill the canal with EDTA solution and use the pre-bent E87/ED87 ultrasonic tip on the inside-of-the-curvature canal wall to loosen and free the file fragment. Even if the separated file is shorter than 4.5mm, it will tend to show more resistance to disengagement as it gets closer to 4.5mm. If this is the case, do not hesitate to use the Endo file remover instead of continuously activating ultrasonics to retrieve it. The empirical findings show that it is faster to use the Yoshi Loop to remove a broken file shorter than 4.5 mm when it doesn’t exit the canal with

ultrasonics in 10 seconds.

3.5 How to Use the Endo file remover

If the separated file is longer than 4.5 mm and it can be seen shaking from ultrasonic activation, or if a separated file shorter than 4.5mm hasn't come out of the canal in 10 seconds of ultrasonic activation, the Endo file remover should be used to capture the coronal portion of the separated file and pull it out of the canal. The canal must be at least 0.4mm wide (the width needed for the Loop wire) in addition to the coronal diameter of the separated file to secure the operative field for the Endo file remover (loop device). In other words, if the broken edge of the file segment gauges at .35mm, the operative space for the Endo file remover would require 0.75mm. Dentin sacrifice to create an extra space for the Endo file remover is typically not significant as the coronal end of a separated file longer than 4.5mm will usually be in the middle third of the root surrounded by a safe thickness of dentin wall (the maximum diameter of most conventional rotary files is between 1-1.2mm so this amount of enlargement is within the size of most root canal shaping objectives). Place a yellow Buchanan plugger to see if there is enough space available for the Endo file remover as the diameter of the #2 Buchanan plugger is a little larger than 0.4 mm. If the tip of this plugger can be placed between the separated file and the space created in the preparation stage, the Endo file remover can also be safely placed in it.



3.5.1 Creating Space for the Endo file remover

If needed, additional space can be most easily created by using the K-ENDO K6 N60 2% L25 file followed by re-use of the appropriate E88/ED88 or E89/ED89 ultrasonic tip on the inside-of-the-curve canal wall.

3.5.2 Preparing the Endo file remover

Once the coronal portion of the separated file is peripherally exposed by at least 0.7 mm on average (e.g., when a 3 mm segment of a 20-.04 rotary file has been left in the canal, the coronal diameter will be around 0.32 mm and the needed operative space is another 0.4 mm wider), the loop size must be adjusted to the coronal end of the separated file with an endodontic explorer such as a DG 16. This is done as follows:

First insert the tip of the explorer into the loop and slide the explorer into the loop until the desired diameter of the loop is met along the length of the explorer's working end. Tighten the loop around the explorer by gently pulling back on the plastic button in the handle, then rotate the explorer to be parallel to the loop cannula to bend the loop at a 45 degree angle to the loop cannula. This allows the end of the loop to enter the trough prepared

space next to the broken file segment, after which the remainder of the loop is pushed back to 90 degrees as it further surrounds the separated file when the loop cannula lands on the file in its final position in the canal.

3.5.3 Removing a File Fragment with Endo file remover

Bring the loop into the canal with the loop cannula on the inside-of-the-curvature side of the file segment and the loop extended toward the outside-of-the-curve side of the file segment and place it over the exposed portion of the separated file. Secure the separated file segment by sliding your finger down on the plastic button-activating it and carefully pull back on it until the loop is felt to tighten around the freed end of the file segment. Feel the tension on the button from tightening the loop around the separated file and gently lift the loop out of the canal while maintaining this tension. Typically, only a single gentle pull will be required to dislodge the file fragment as the separated file is already loosened. If you feel greater resistance from lifting the Loop, try pulling it in 12 o'clock, 3 o'clock, 6 o'clock, and 9 o'clock directions, one of which will eventually result in instrument Removal depending on the free space available in the canal to let it pass through.

If the Loop is felt to slip off the file fragment, simply remove the Loop, again create a round shape in the micro-lasso by tightening it around the appropriate diameter of a DG-16 explorer, rotate the explorer parallel to the loop cannula to bend it to a 45 degree angle, re-insert it and re-engage the file segment. On occasion, it will require several attempts for lack of tightening strength before the file comes out. Be certain, before using the Loop, that the file segment has been loosened by the ultrasonic tips before attempting to remove it with the Loop. The separated file also has to be tightened firmly with the Loop while the tension on the loop is maintained securely enough not to slip off the file fragment as it is being pulled out. Do not mistake its flexing for it being loose as a long separated file segment is apt to flex with ultrasonics, seeming to be loosened when in fact it is still engaged in the canal wall and not yet ready to be removed with the Loop.

Never tighten the Loop against the cannula end when it is not engaged around an explorer or file segment as this will kink and weaken the micro-lasso wire, accelerating its failure.

4 Safety precautions

4.1 For repairs and purchase of spare parts, please contact our authorized supplier.

4.2 Read this operating manual before use and fully understand the functions of each part.

4.3 Do not cut the K-ENDO K6 N60 2% L25 File or the TFRK burs to the broken file edge when the curvature of the canal is over 30° or the end of the separated file is in the apical one third of the canal to avoid perforation.

4.4 Sterilize before use.

4.5 These instruments are limited to professional dentists only.

5 Cleaning, disinfection and sterilization

5.1 Endo file remover

5.1.1Automated cleaning

Automatic cleaning must be performed with an automatic cleaning instrument conforming to EN ISO 15883. The cleaning requirements are as follows:

(1)Remove the handle long rod, handle short rod, lock nut, and needle core, and rinse away the dirt on the surface of them with pure water (or distilled water/deionized water)

(2) Dry the product with a clean, soft cloth and place them in a clean tray.

(3) Carefully place the products into the washer-disinfector .

(4) Start the program of the washer:

(5) 3 min pre-washing with cold water(<40°C);

(6) Clear

(7) Wash with neodisher MediZym (Dr. Weigert) diluted with deionized water (<45°C) for 5 minutes;

Cleaning Agent: neodisher MediZym

(8) Clear

(9) Rinse with cold deionized water for 1 minuter (<40°C);

(10) Clear

(11) Rinse with cold deionized water for 1 minuter (<40°C);

(12) Clear

(13) Drying 20 minutes

Notes :

(1) If the automatic cleaning equipment has no automatic drying function, it is necessary to use a clean absorbent soft cloth to wipe the residual water stains on the surface of the sample.

Methods:

-Spread a clean white paper (white cloth) on the flat table, point the products against the white paper (white cloth), and then dry the products with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

-It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃ ～ 120℃ and the time should be 15 ～ 40 minutes.

(2) Visual inspection:

Before packaging and auto sterilization, make sure that the product has been cleaned according to manufacturer's instruction. Visually check the integrity and cleanliness of the cartridge holder:

—If there is still visible stain on the product after cleaning, the entire cleaning process must be repeated.

—If the appearance of the cartridge holder is obviously damaged, crushed, fallen off, corroded or bent, it must be scrapped and not allowed to continue to be used.

5.1.2 Disinfection

N/A. The products must eventually be sterilized, so the disinfection process is not applicable.

5.1.3 Sterilization

(1) Pack the product in an appropriate packaging material for sterilization.The packaging material and system refer to EN ISO 11607.

(2) Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

(3) The sterilization program should include the following key parameters:

Sterilization time:5 minutes

Pressure： 2.0 bar ~ 2.3 bars

Temperature: 134℃

Drying time： 20 minutes.

Note :

The cartridge holder that has been sterilized should be placed in a sterilization packaging, and then taken out before use. The packaging material shall meet the requirements of EN ISO 11607.

After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.

Please use the recommended sterilization procedures . It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

5.1.4 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

c) Before use, pay attention to check the packaging, if it is damaged, please rinse and sterilize before use.

5.2 Dental Explorer

5.2.1Automated cleaning

Automatic cleaning must be performed with an automatic cleaning instrument conforming to EN ISO 15883. The cleaning requirements are as follows：

(1) Rinse away the dirt on the surface of the device with pure water (or distilled water/deionized water)

(2) Dry the product with a clean, soft cloth and place them in a clean tray.

(3) Carefully place the products into the washer-disinfector .

(4) Start the program of the washer:

(5) 3 min pre-washing with cold water(<40°C);

(6) Clear

(7) Wash with neodisher MediZym (Dr. Weigert) diluted with deionized

water (<45℃) for 5 minutes;

Cleaning Agent: neodisher MediZym

(8) Clear

(9) Rinse with cold deionized water for 1 minuter (<40°C);

(10) Clear

(11) Rinse with cold deionized water for 1 minuter (<40°C);

(12) Clear

(13) Drying 20 minutes

Notes :

(1) If the automatic cleaning equipment has no automatic drying function, it is necessary to use a clean absorbent soft cloth to wipe the residual water stains on the surface of the sample.

Methods :

-Spread a clean white paper (white cloth) on the flat table, point the products against the white paper (white cloth), and then dry the products with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

-It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃ ～ 120℃ and the time should be 15 ～ 40 minutes.

(2) Visual inspection:

Before packaging and auto sterilization, make sure that the product has been cleaned according to manufacturer's instruction. Visually check the integrity and cleanliness of the cartridge holder:

—If there is still visible stain on the product after cleaning, the entire cleaning process must be repeated.

—If the appearance of the product is obviously damaged, crushed, fallen off, corroded or bent, it must be scrapped and not allowed to continue to be used.

5.2.2 Disinfection

N/A. The products must eventually be sterilized, so the disinfection process is not applicable.

5.2.3 Sterilization

(1) Pack the product in an appropriate packaging material for sterilization.The packaging material and system refer to EN ISO 11607.

(2) Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements.

(3) The sterilization program should include the following key parameters:

Sterilization time:5 minutes

Pressure： 2.0 bar ~ 2.3 bars

Temperature : 134℃

Drying time： 20 minutes.

Note :

(1) The product that has been sterilized should be placed in a sterilization packaging, and then taken out before use. The packaging material shall meet the requirements of EN ISO 11607.

(2) After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it

should be reprocessed before use.

(3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.

(4) Please use the recommended sterilization procedures . It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

5.2.4 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

c) Before use, pay attention to check the packaging, if it is damaged, please rinse and sterilize before use.

5.3 Tips of Ultrasonic Scaler

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

This device shall not be exposed to high temperature above 138℃.

Processing limit:

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for tips is 300 times.

5.3.1 Initial processing

1.Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and productspecific procedures are used for cleaning/ disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

2.Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

3. Let the Ultrasonic Scaler works for 20-30 seconds under irrigation mode to flush the handpiece and tip;

4. Remove the handpiece from the Ultrasonic Periodontal Treatment Device, and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water);

5.3.2 Dry the product with a clean, soft cloth and place it in a clean tray.

Notes:

a) The water used here must be pure water, distilled water or deionized water.

5.3.3 Preparation before cleaning

Steps:

Tools: Endo wrench or 1# torque wrench, tray, soft brush, clean and dry soft cloth

1. Remove the tip from product with endo wrench or 1# torque wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd, and then put the tip and wrench into a clean tray.

2. Then use soft cloth to dry the product and accessories and put them into a clean tray.

3.Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

5.3.4 Automated cleaning

• The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

• There should be a flushing connector connected to the inner cavity of the product.

• The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section “Disinfection”.

Notes:

a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c) After cleaning, the chemical residue should be less than 10mg / L.

5.3.5 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

5.3.6 Automated disinfection-Washer-disinfector

· The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

·Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

·The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washerdisinfector.

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section “Inspection and Maintenance”) and packaging (refer to chapter “Packaging”). Dry the product repeatedly if necessary (refer to section “Drying”).

Notes:

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600

(d2) For the disinfection here, the temperature is 93° C, the time is 2.5 min, and A0>3000

e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning, the chemical residue should be less than 10mg / L.

g) The air used for drying must be filtered by HEPA. h) Regularly repair and inspect the disinfector.

5.3.7 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃ ～ 120℃ and the time should be 15 ～ 40 minutes.

Notes:

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

5.3.8 Inspection and maintenance

In this chapter, we only check the appearance of the product.

1. Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

2. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

3. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

5.3.9 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Notes:

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

d) Avoid contact with parts of different metals when packaging.

5.3.10 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

2. The highest sterilization temperature is 138 ° C;

3. The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.

4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Notes:

a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

d) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

5.3.11 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a

relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

5.4 Dental Root Canal Instruments

5.4.1 Disassembling: Remove the stopper from the instrument and dispose of it

5.4.2 Rinsing: Rinse extensively (at least 1 minute) under flowing deionized water

(ambient temperature). While rinsing, use a soft brush (made of nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.

5.4.3 Cleaning and Disinfection

5.4.3.1Manual Cleaning assisted by an ultrasonic device:

1) Manual cleaning with ultrasonic equipment

2) Place the instrument in a kit, stand or container (made of stainless steel, polypropylene or titanium).

3) Immerse in a detergent solution(for example, Metrex EmPowder concentration 1:128) with cleaning properties, if appropriate, soak for at least 15 minutes with the aid of ultrasonic equipment.

4) Flushing: Perform a large amount of flushing (at least 1 minute) under flowing deionized water temperature 20°C ~ 40°C.

5) Drying: Dry with a disposable non-woven fabric or hot air dryer not exceeding 110°C.

5.4.3.2 Automated Cleaning using a cleaning and disinfecting device

1) Place the instrument in a kit, stand or container (made of stainless steel or titanium).

2) Perform the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 ~ 1:512) for at least 5 minutes in the washer-disinfector with temperature 20°C ~ 40°C.

5.4.3.3 Disinfection using a washer-disinfector device

1) Place the instrument in a kit, stand or container (made of stainless steel or titanium).

2) Perform the defined cycle with mild neutral enzyme cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector with temperature >90°C, A0 >3000.

Note:

-> Discard any instruments with obvious defects (broken, bent, etc.).

-> When the instruments are placed in the cleaning kit, support or container, avoid any contact with each other.

-> Follow the instructions and concentration provided by the detergent solution manufacturer (see also general recommendations).

-> Follow the instructions of the washer-disinfector and verify the success criteria after each cycle is reached according to the manufacturer's instructions.

-> The final rinse step should use deionized water. For other steps,

follow the water quality defined by the manufacturer. Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts.

5.4.3.4 Rinsing: Abundant rinsing (at least 1 min) under running water (ambient temperature).

1) Use deionized water for rinsing.

2) If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.

5.4.3.5 Drying: Devices should be thoroughly dried before inspection and packaging.

1) Dry on a single use non-woven cloth, or with a hot air drier at not more than 110°C.

2) Devices should be dried until visual traces of moisture are eliminated.

3) Particular attention has to be paid to effectively dry joints or cavities within a device.

5.4.3.6 Inspection:

5.4.3.7 Inspect the devices functionality.

5.4.3.8 Inspect devices and sort out those with defects.

1) Dirty devices must be cleaned again.

2) Do not re-use silicon stops.

3) Discard devices, which show any defect

5.4.3.9 Packing: Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in "Sterilization pouches".

1) Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers.

2) For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.

3) Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated.

4) Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.

5.4.4 Sterilization:

1) Steam sterilization at 132°C / 273°F during 4 min is recommended for these devices, for the purpose of de- activating potential prions.

2) The instruments and posts must be sterilized according to the packaging labelling.

3) Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer.

4) Use only steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer), EN 285 (full size sterilizer).

5) Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min

6) Respect the maintenance procedure of the sterilizer given by the sterilizer manufacturer.

7) Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters).

8) Store traceability records and define shelf-life according to packaging manufacturer guidelines.

9) Shorter sterilization cycles according to local regulations are possible

but are not guaranteed to de-activate prions.

5.4.5 Storage

Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.

1) Sterility cannot be guaranteed if packaging is open, damaged or wet.

2) Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).

6 Transportation

1. Excessive shock and vibration should be prevented during transportation, and handled with care;

2. Transport should not be mixed with dangerous goods.

3. Avoid exposure to sun or rain or snow during transportation.

7 General safety instructions

Before use, check that the instrument has not been damaged. No modifications to the instrument may be made without the express permission of the company.

8 Instrument hygiene

The instrument is not delivered sterile. Before use, the instrument must be sterilized.

9 Disposal

The relevant statutory provisions regarding the disposal of medical waste apply.

10 Symbol instruction

	Manufacturer
	Date of manufacture
	Can beautoclaved
	Follow Instructions for Use
	Medical Device

Scan and Login website
for more information

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